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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,283	02/23/2002	Laura L. Dugan	53047/31628	4140
70119 7590 04/19/2007 THOMPSON COBURN LLP ATTN: RICHARD E. HAFERKAMP ONE U.S. BANK PLAZA SAINT LOUIS, MO 63101			EXAMINER ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/083,283

Applicant(s)

DUGAN ET AL.

Examiner

Leslie A. Royds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>31 January 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-12 and 70-72 are presented for examination.

Applicant's Amendment and Information Disclosure Statement filed January 31, 2007 have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references.

Claims 1, 3-12 and 70-72 are pending and under examination. Claims 1 and 70 are amended and claims 71-72 are newly added.

Applicant's arguments, filed January 31, 2007, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6-12 and 70-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth at pages 2-5 of the previous Office Action dated October 10, 2006, of which said reasons are herein incorporated by reference.

The instant rejection is maintained insofar as it applies to the lack of written description for the genera of pharmaceutically acceptable esters or amides of the claimed C60 compounds. The rejection has been withdrawn insofar as it was applied to a lack of written support for executing the claimed process in a mouse cell or human cell.

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Newly added claims 71-72 are properly included in the instant rejection because they are directed to the use of pharmaceutically acceptable esters or amides of the presently claimed C60 compounds.

Applicant traverses the instant rejection, stating that, with regard to a lack of written support for pharmaceutically acceptable esters or amides, Applicant alleges that such embodiments are clearly supported by the specification (see, e.g., page 13, lines 1-3), and further alleges that pharmaceutically acceptable esters and amides of carboxylic acids were well known to the of skill in the art at the time of filing. Applicant relies upon U.S. Patent No. 4,705,781 in support of the assertion that pharmaceutically acceptable esters and amide of carboxylic acids were well known in the art at the time of filing.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, it is noted that the issue at hand is whether Applicant has provided sufficient direction to one of ordinary skill in the art to determine the metes and bounds of the claimed genera of pharmaceutically acceptable esters and amides *of the presently claimed C60 compounds*. Though the art may recognize various methods of carboxy-esterification and formation of amides from carboxylic acids, it remains that the art upon which Applicant relies in order to demonstrate that such techniques were well known in the art (i.e., U.S. Patent No. 4,705,781) are directed to piperazine-based heterocyclic compounds and not the much more highly complex C60-fullerene compound. Accordingly, reliance upon such art to demonstrate that the formation of pharmaceutically acceptable esters or amides of the claimed C60 compounds was well known in the art at the time of the invention is clearly not persuasive in establishing error in the propriety of the instant rejection because the cited art is not relevant to the claimed genus of C60 compounds and, therefore, fails to establish that such esterified or amidated compounds were well known in the art at the time of the invention.

Furthermore, it is noted that Applicant has failed to provide any degree of derivation that a compound may have from the parent C60 compounds and still be considered a pharmaceutically

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acceptable ester or amide suitable for use in the present invention. Absent such direction, it remains that the skilled artisan would not have been reasonably apprised of the scope of the claimed genera of "pharmaceutically acceptable esters or amides" because there is no guidance as to what elements of the compound must be preserved in order to retain its function in achieving the claimed objective. Moreover, due to the very complexity of a C60 fullerene compound, random esterification or amidation (particularly multiple esterifications or amidations) of the compounds, in the absence of any direction as to the locations suitable for such esterification or amidation and/or the number of times the compound could conceivably be esterified or amidated, would have been reasonably expected to alter the structure and/or function of the molecule due to steric effects, which would have been reasonably expected to constructively alter the conformation and reactivity of the molecule, especially due to the close proximity and interaction of adjacent side groups as a result of the spherical nature of the fullerene.

In view of this knowledge, and absent any direction or guidance by Applicant to reasonably apprise the skilled artisan of the metes and bounds of the genera of pharmaceutically acceptable esters or amides, one of skill in the art would have been obligated to execute hit or miss testing practices to determine those esters and/or amides of the claimed C60 compounds amenable for use in the present invention. The need for testing amongst widely varying species of compounds to determine the full scope of the claimed genera of pharmaceutically acceptable esters and amides clearly demonstrates that Applicant was not in possession of the full scope of the genera now presently claimed. As stated in the MPEP §2163, "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention."

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For these reasons provided *supra*, and those previously made of record at pages 2-5 of the previous Office Action dated October 10, 2006, rejection of claims 1, 3-4, 6-12 and 70-72 is proper and is **maintained**.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-12 and 70-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for extending the lifespan of mice comprising the administration of the C60 compound *e,e,e*, C60(C(COOH)2)2(CHCOOH); *e,e,e* C60(CHCOOH)3; C60(C(COOH)2)*n*, and the pharmaceutically acceptable salts thereof, does not reasonably provide enablement for extending the lifespan of a human (or a cell thereof) comprising the administration of the same, for the reasons of record set forth at pages 5-14 of the previous Office Action dated October 10, 2006, of which said reasons are herein incorporated by reference.

Newly added claims 71-72 are properly included in the instant rejection because such claims are directed to the execution of the claimed process for extending lifespan in a human cell thereof.

Applicant's remarks have been fully considered in their entirety, but again fail to be persuasive as they relate the concept of extrapolating the longevity extending results demonstrated in the C57B6NIH mice of Example 2 to humans.

Mice Are an Art-Accepted Model for Extending Lifespan

Applicant reiterates the reliance upon the Roth publication as being demonstrative of the fact that mice are art-accepted models for lifespan extension. Applicant agrees that better models are desirable to

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study human aging, but that the model systems that have been adopted as predictive in humans are those that necessarily take into account practical considerations. Applicant reiterates, "The question at hand is not what model theoretically is the most predictive, but rather what models are widely recognized in the art as having predictive value." Applicant asserts that rodent models are, and have been, the most widely accepted model for the study of aging with potential relevance to human aging and age-related disease.

Applicant is relying on the predictive efficacy of the rodent model in order to extrapolate the results demonstrated in Applicant's Example 2 to the same or substantially similar efficacy in humans. Accordingly, it is crucial to such an argument to show that the rodent model is, in fact, a predictive model of human efficacy in aging and lifespan extension, which is clearly missing from both the specification and Applicant's remarks and, moreover, is not recognized in the art. Though Applicant asserts that it is not necessary to show what model is theoretically the most predictive, such an assertion is clearly erroneous because the very basis for extrapolating rodent efficacy to human efficacy must be firmly grounded in the expectation that the results in the rodent model are predictive of that in the human model. Absent such a correlation, one of skill in the art would clearly doubt that the efficacy shown in mice would be predictive of the same or substantially similar efficacy in humans.

Roth does not provide this correlation. Though Roth notes that rodents are widely used as animal models for gerontology and that studies in invertebrates have provided some insight into the *aging process*, such statements provided in Roth do not equate to the generalization that rodents are recognized in the art as reasonably predictive of the same or substantially similar level of efficacy in humans. In fact, as previously stated, Roth et al. expressly states to the contrary: "*Given the complexity of human physiology, however, models more phylogenetically similar to humans are needed.*" In other words, while Roth et al. teaches the use of rodent models in aging experiments, Roth et al. also casts doubt on the predictive value of such a model by the fact that mice are not phylogenetically similar to humans. The

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statement of a need for a more relevant animal model presents a clear basis for the skilled artisan to have reservations about the predictive efficacy of a rodent model.

Mice Have Been Used to Study Potential Life-Extending Treatments in Humans

Applicant relies upon the study of resveratrol in mice on a high-calorie diet, which was expected to recapitulate the lifespan extending benefits of caloric restriction without subjecting an organism to reduced calorie intake. Applicant states that the study showed that an orally available small molecule at doses achievable in humans could safely reduce many of the negative consequences of excess caloric intake with an overall improvement in health and survival. Applicant urges the similarity between Baur et al. and the instant invention (i.e., that an unrelated small molecule can extend lifespan without calorie restriction) and that Baur et al. would not have tested concentrations feasible for humans if the mouse model had not been selected for its predictive value in humans.

While the results of Baur et al. have been fully and carefully considered, it remains that the study solely presents data in the rodent model and none in a human model. As a result, the publication is merely speculative about the predictive efficacy of the administration of the resveratrol therapy in mice to achieving the same health and survival-improving effects in humans, absent factual evidence to the contrary.

Baur et al. certainly supports the enablement of the instant invention insofar as it reads upon the extension of lifespan in a mouse, but provides no basis for extrapolating the efficacy of resveratrol in a rodent model to a human model with a reasonable expectation of success in achieving the same (or at least a substantially similar) result. Furthermore, it is noted that resveratrol is an extract from the skin of red grapes and, therefore, is generally accepted in the art as being a non-toxic naturally occurring food-based compound with its own health-improving effects, which would have been expected to increase survival by improving health. On the other hand, however, the presently claimed carboxylated C60

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compounds are highly complex and must be chemically synthesized, i.e., not naturally occurring, such that the efficacy and general acceptability of the small molecule resveratrol fails to raise the same concerns as, for example, the administration of a synthesized C60 carboxylated fullerene compound, which differs so significantly in structure and function that one of ordinary skill in the art at the time of the invention would not have viewed the results of resveratrol as being representative of the same, or at least substantially similar, level of efficacy in achieving the same result with a carboxylated C60 compound.

Kuro-o Teaches that C57BL/6 Mice Are an Art-Accepted Model Predictive of Human Aging

Applicant states that the Examiner is confusing rodent genetic mutation(s) (i.e., *klotho* mouse) with a rodent strain (i.e., C57B6) and further states that, with the exception of the senescence-accelerated mouse (SAM), the *klotho* mouse was developed on a C57BL/6 background crossed with the C3H/J strain and the *WRN* mouse was also generated on a C57BL/6 background. Applicant alleges that the models presented by the Kuro-o reference simply teaches various uses of the C57BL/6 mouse strain and, therefore, Kuro-o gives several examples of the use of the same mouse strain as that employed by Applicant in Example 2. Applicant relies upon the “jaxmice”, “aceanimals” and “genome.gov” references in support of the assertion that the C57BL/6 strain is the most commonly used laboratory inbred mouse strain and further alleges, “Clearly, Kuro-o is asserting that mouse models (including the C57BL/6 strain) are predictive of human aging.”

The Examiner has duly noted Applicant’s discussion with regard to the differences between a mouse strain and a genetically mutated mouse.

However, Applicant asserts that the *klotho* mouse and the *WRN* mouse taught by Kuro-o are generated on a C57BL/6 background and that the teachings of Kuro-o support the use of the C57BL/6 as used by Applicant for human aging, but provides no evidence in support of these allegations. The

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“jaxmice”, “aceanimals” and “genome.gov” references, as well as the entirety of the Kuro-o reference have been fully and carefully considered, but no teachings of the use of a base C57BL/6 mouse to produce, for example, the *klotho* or *WRN* mouse, could be located. Accordingly, such remarks are no more than allegations without factual support and are not persuasive in establishing that Kuro-o, in fact, supports the use of a C57BL/6 mouse as being predictive of human aging. Please see, e.g., MPEP §716.01(c)[R-2](II), which states, “The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).”

Furthermore, though the “jaxmice”, “aceanimals” and “genome.gov” references state that the C57BL/6 mouse strain is a widely used (“jaxmice” or “aceanimals”) or a preferred mouse strain (“genome.gov”), such statements do not support the conclusion that C57BL/6 mice are the *only* mice available for use and, therefore, that they must necessarily be the mouse strain upon which the models of Kuro-o are based. Such a generalization made solely on the basis of the popularity of the mouse strain is not supported by factual or scientific evidence and is, therefore, not persuasive in establishing that Kuro-o supports the use of a C57BL/6 mouse as a predictive model of human aging.

Administration of a C60 Compound Could be Expected to Extend Longevity Across Species

Applicant again relies upon Baur et al. to show that by targeting a pathway implicated in calorie restriction, one could achieve lifespan extension without a reduction in caloric intake, which is the exact same premise behind Applicant’s current invention, i.e., the use of molecules that reduce oxidative stress. Applicant further asserts that Baur et al. is a clear example that those skilled in the art believe that the lifespan extending effects of calorie restriction can be achieved independent of actual calorie restriction. Applicant submits that it is not the act of calorie reduction, but the subsequent physiological response that leads to lifespan extension. Applicant additionally relies upon the fact that Baur et al. clearly indicates that one skilled in the art would predict that the administration of a small molecule to achieve lifespan

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extension in humans is an achievable goal and that the fact that Baur et al. uses concentrations of resveratrol achievable in humans is clearly indicative of the fact that the mouse model was expected to be predictive of resveratrol administration in humans. Applicant alleges that the specification provides ample scientific reasoning as to why the *in vivo* animal results are suggestive of human efficacy and ample guidance as to how one would practice the claimed method (i.e., dosage amounts, timing and methods of administration, etc.)

Applicant has taken these remarks out of context of the discussion presented in the rejection. First, it is noted that the remarks of the Examiner presented at pages 9-10 were made in response to Applicant's allegations that, since calorie restriction was a known method of lifespan extension that could be used in various species, then one of skill in the art would have reasonably expected the lifespan-extension shown in mice would have also been predictive of efficacy across species. The discussion of the simplicity of calorie restriction versus the complexity of the claimed process was relevant solely to the fact that one of skill in the art at the time of the invention would have been skeptical to extrapolate Applicant's efficacy demonstrated in a mouse model to a human on the grounds that since calorie restriction, a known method of lifespan extension, could achieve such an objective "across species", then the claimed process would also be relevant across species, i.e., humans.

Regardless, however, the relevance of Applicant's discussion regarding the fact that Baur et al. clearly shows that one could achieve lifespan extension without a reduction in calorie intake is, respectfully, not clear. It was not suggested that one of skill in the art would only have expected calorie restriction to work; it is simply that this is one of the only methods that has been predictably shown to work across various species. However, the simplicity of achieving calorie restriction and the complexity of the claimed process precludes the extrapolation of Applicant's results in mice to humans (or other mammals, for that matter) based solely upon the idea that one other (and a notably more simplistic method) is known to work in various species aside from mice alone.

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Once again, as stated *supra*, it is reiterated that Baur et al. is merely speculative about the predictive efficacy of the administration of the resveratrol therapy in mice to achieving the same health and survival-improving effects in humans. Though Baur et al. suggests the *adaptation* of a similar therapy in humans, Applicant is again attempting to rely upon his presumption that the rodent model used in Baur et al. predicts the same efficacy in humans in the absence of an explicit, or implicit, suggestion to that effect. Further, given, at minimum, the Kuro-o reference cited by the Examiner, it is clear that such a model is *not* an art-accepted model of human aging, absent factual evidence and despite Applicant's allegations to the contrary, and that Applicant has clearly not rebutted the evidence of unpredictability and skepticism in the art at the time of the invention.

Additionally, the Examiner has duly noted Applicant's remarks regarding the provision of ample guidance on dosage amounts and methods and timing of administration(s). However, the Examiner did not intend to imply that the presently claimed invention did not provide such enabling direction as to how one of skill in the art would go about determining the appropriate dosage and/or route and/or schedule of administration, but rather to note that the consideration of such factors add further complexity to the claimed process as a whole.

C57BL/6 Mice Are Not a Calorie Restricted Strain of Mice

Applicant argues against the assertion that the C57BL/6 mouse strain is a calorie-restricted strain at pages 18-19 of the remarks.

Applicant's remarks have been fully considered by the Examiner and are persuasive in establishing that the C57BL/6 mouse strain is not *exclusively* a calorie-restricted strain.

Inbred Strains and The Possibility of Other Genetic Mutations

Applicant argues that researchers use inbred strains of mice for the express purpose of avoiding the confounding effects of genetic variability in experiments. Applicant further submits that, while there is a very remote possibility that perhaps one or two of the inbred mice in the study somehow sustained a spontaneous mutation, the scenario where only the treated mice that exhibited longevity effects were comprised of mutants that increased longevity while the untreated mice were wild-type is essentially impossible.

First, the remarks set forth by the Examiner were not predicated on the grounds that *all* of the tested mice had genetic mutations that resulted in longevity beyond the control mice and, thus, that the C60 compounds had no effect on longevity. Rather, it would have been expected that the mutations, if any, would have occurred randomly and infrequently given the control and the monitoring of the colonies used so as to avoid such genetic mutations. However, due to the small sample size, the presence of even a single mutation out of the total population of less than 20 mice would have a significant impact on the final result of the control mice versus the treated mice.

Applicant's citation of the NIA webpage regarding "Colony Monitoring and History" has been fully considered and noted, but supports the idea that there *is* a possibility of genetic mutations in the mice. The fact that the NIA strives to keep substrain differentiation to a minimum is a laudable goal, but would be expected to be impossible to achieve colonies wherein substrain differentiation was essentially 0%. Accordingly, the fact that the mice used in Applicant's experiments were inbred does not necessarily preclude the existence of other, possibly silent, genetic mutations in the mice that may have been responsible either for either an early or a delayed demise. Since lifespan is a relative phenomenon that varies by individual subject, the presence of even a single mutation in a control mouse would skew the results if such a mutation resulted in an early demise. As a result, the genetic makeup of the mice used

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and the presence of any genetic mutations is, *in fact*, pertinent to the interpretation of the data proffered in Example 2, despite Applicant's assertions to the contrary.

Undue Experimentation Required to Practice the Claimed Invention in Humans

Applicant maintains that, given the knowledge in the pharmaceutical arts at the time of the invention, and further in view of the direction provided in the specification, that undue experimentation would not be required to practice the instant invention in humans. Applicant further relies upon the admission in the Office Action stating that experimentation in this art is not uncommon and asserts that any experimentation needed to practice the invention would be routine and not undue.

It is true that the state of the pharmaceutical arts generally requires, and continues to require, routine experimentation. However, the basis for the instant rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, *but that the experimentation in order to practice the claimed invention in humans, given the demonstration of efficacy solely in rodents, would be undue in light of the knowledge of animal aging models in the art at the time of the invention.* Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue.*" (emphasis added)

As previously stated at page 14 of the Office Action dated October 10, 2006, *In re Brana* and MPEP §2164.02 direct, "Even with such evidence, the Examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995)." Respectfully, in light of the discussion *supra* and the remarks previously presented, the evidence against accepting the rodent model of Example

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2 as reasonably correlating to the same efficacy in humans outweighs the evidence in favor of accepting the model as correlating to the same efficacy in humans.

For these reasons, and those previously set forth at pages 5-14 of the Office Action dated October 1, 2006, rejection of claims 1, 3-12 and 70-72 is proper and is **maintained**.

Conclusion

Rejection of claims 1, 3-12 and 70-72 is proper and is **maintained**.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

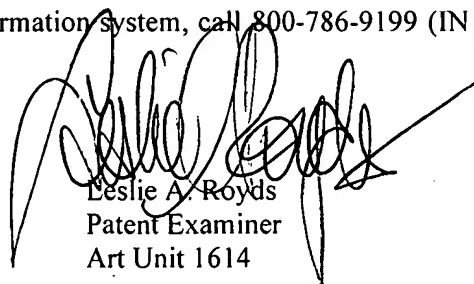
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds
Patent Examiner
Art Unit 1614

April 10, 2007



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER